DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

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NOV - 5 2001

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

Damon P. Miller II, M.D.
881 Freemont Avenue, Suite A5
Los Altos, California 94024

Re: MicroStim 100-2C, MicroStim 100i,
K910580; K010295

Dear Dr. Miller:

The Office of Compliance (OC), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) has reviewed your web site at the Internet address: http://www.acupunctureworks.com for the MicroStim 100-2C and MicroStim 100i products. These products are manufactured by MicroStim Technology, Incorporated and are devices as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Both the MicroStim 100-2C and the MicroStim 100i were cleared through the 510(k) premarket notification process as Transcutaneous Electrical Nerve Stimulation (TENS) devices. The MicroStim 100-2C and the MicroStim 100i are intended for the symptomatic relief of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post-surgical traumatic pain problems.

The beginning of your web site (http://www.acupunctureworks.com/micro.htm) includes a broad discussion of Microcurrent Stimulation. There you discuss how Microcurrent Stimulation is used for treating problems in the muscles, joints, tendons, and bones; the reduction of scar formation following plastic surgery; treating acute sports injuries, non-healing bone fractures, retinal disease, and other eye diseases such as the wet and dry forms of macular degeneration and the treatment of Stargardt's disease.

Other sections of your web site specifically mention the use of the MicroStim 100-2C and the MicroStim 100i, manufactured by Microcurrent Technology, for the treatment of age-related macular degeneration. In these sections, you discuss your use of the Microstim devices in the treatment of age-related macular degeneration. You state that your patient's vision improved by becoming clearer and brighter. Additionally, you indicate that of 120 patients treated in your office, 101 (83%) of those patients showed improvement greater than or equal to two lines of visual acuity in one or both eyes. You further state that if you were to include those patients who

had at least one line of improvement in visual acuity, your success rate jumps to 93%.

We advise you that claims for the treatment of age-related macular degeneration or any other disease conditions (not specifically cleared) represent a major modification in the intended use of these devices as described at 21 CFR 807.81(a)(3)(ii) and require the submission of a new 510(k).

The intended use of a device is defined under 21 CFR 801.4 as the objective intent of persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

Promoting the MicroStim 100-2C and/or the MicroStim 100i for claims of age-related macular degeneration is a violation of the law and causes them to be misbranded within the meaning of section 502(o) of the Act, in that a notice or other information respecting the modification in the intended use of the devices was not provided to FDA as required by 21 CFR 807.81(a)(3)(ii) and section 510(k) of the Act.

The MicroStim 100-2C and the MicroStim 100i are also adulterated within the meaning of section 501(f)(1)(B) of the Act in that they are Class III devices under section 513(f), and do not have approved applications for premarket approval (PMA) in effect pursuant to section 515(a), or approved applications for investigational device exemptions (IDE's) under section 520(g).

We also note that portions of your web site discuss the use of a device you refer to as the Micro-Stim 400-III. The agency has no information as to the marketing status of this device. Please provide the cleared 510(k) number for this device.

This letter is not intended to be an all-inclusive list of deficiencies associated with the use of your MicroStim 100-2C and 100i devices. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used in your practice. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District Office. Please send a copy of your response to the District Director, Food and Drug Administration, San Francisco District Office (HFR-PA100), 1431 Harbor Bay Parkway, Alameda, California 94502-7070.

Sincerely yours,

Jerri D. Garrison for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health